Interested persons may, on or before December 18, 1990, review the petition and/or file comments (two copies, identified with the docket number found in brackets in the heading of this document) with the Dockets Management Branch (address above). Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. A copy of the petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 11, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90-24704 Filed 10-18-90; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90E-0266]

Determination of Regulatory Review Period for Purposes of Patent Extension; Ergamisol®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Ergamisol® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Ergamisol®. Ergamisol® (levamisole HCl) is indicated as adjuvant treatment in combination with fluorouracil after surgical resection in patients with Dukes' stage C colon cancer. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Ergamisol® (U.S. Patent No. 4,584,305) from Janssen Pharmaceutica N.V., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated August 23, 1990, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period. The letter also stated that the active ingredient, levamisole HCl, represented the first permitted commercial marketing or use under the provision of law governing regulatory review of human drug products. Levamisole HCl had previously received permission for commercial marketing or use under the provision of law governing regulatory review of animal drugs. Shortly thereafter, the Patent And Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Ergamisol is 4,833 days. Of this time, 4,603 days occurred during the testing phase of the regulatory review period, while 230 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* March 27, 1977. The applicant claims April 8, 1977, as the date the investigational new drug (IND) application became effective. However, FDA records indicate that the IND effective date was March 27, 1977, which was 30 days after FDA receipt of the IND application.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* November 1, 1989. FDA has verified the applicant's claim that new drug application (NDA) 20-035 was submitted on November 1, 1989.

3. *The date the application was approved:* June 18, 1990. FDA has verified the applicant's claim that NDA 20-035 was approved on June 18, 1990.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 422 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before December 18, 1990, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before April 19, 1991, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 am. and 4 pm., Monday through Friday.

Dated: October 12, 1990.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 90-24702 Filed 10-18-90; 8.45 am]

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